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510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Ventana Medical Systems, Inc. developed Ventana Anti-Keratin-AE1 Primary Antibody (Clone AE1) for use on the Ventana ES Automated Slide Stainer. Ventana Anti-Keratin-AE1 Primary Antibody (Clone AE1) is substantially equivalent to a commercially available anti-human cytokeratin (clone CAM 5.2).

Comparative Study

Supporting data for the equivalence statement is shown by literature and the following study. Paraffin embedded preparations from normal and pathologic samples were tested using Ventana Anti-Keratin-AE1 Primary Antibody. Samples were obtained from excess tissues obtained for reasons other than the present study. Pathologic tissues evaluated for staining included breast carcinomas, melanomas, squamous cell carcinomas, carcinoids, and leiomyosarcomas. Normal tissues examined were breast, ureter, thyroid, skin, small intestine, stomach, liver, smooth muscle, prostate, tonsil, pituitary, thymus, esophagus, ovary, testes, pancreas, cardiac muscle, spinal cord, spleen, adenoid, and kidney. Slides were processed on the Ventana ES Automated Slide Stainer and prepared for examination, then evaluated for specific staining intensity and background staining. These results were compared to data generated using a commercially available keratin antibody CAM 5.2.

Results

Specificity and sensitivity of both antibodies was shown by appropriate staining of cells of epithelial origin and no staining of cells of mesodermal or endodermal origin. The antigenic sites for the Clone AE1 antibody have a different mix of subfamilies than the antigens detected by CAM 5.2, but there is crossover staining between the two antibodies. In the present study Anti-Keratin-AE1 Primary Antibody (Clone AE1) stained positively in 18 of 18 epithelial cancers compared to Anti-Keratin Primary Antibody (Clone CAM 5.2) which stained positively with 31 of 36 carcinomas tested.

Inter-run reproducibility of staining was based on samples of the same tissue on 15 different instrument runs with Anti-Keratin Antibody Clone AE1 and Ventana DAB detection kit and intra-run reproducibility of staining was based on 10 samples of the same tissue within one run, with Anti-Keratin-AE1 Primary Antibody (Clone AE1) and Ventana DAB detection kit. All slides stained with equivalent staining intensity.